Operational Support Tool 300-00-06D

Unreviewed Safety Question Process Quality Review Guidance

Los Alamos National Laboratory

Developed by

Facility and Waste Operations Division
Office of Authorization Basis

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HISTORY OF REVISIONS

Revision	Date	Summary
0	06/12/01	Issued for review;
1	07/26/01	Updated to incorporate DOE and Facility comments;

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1.0 PURPOSE

The purpose of this document is to provide a set of review guidelines and expectations to ensure that the technical quality of USQ process applicability assessments, screens, and determinations is high and that reviewers apply consistent guidelines in the review of USQ documents.

This document provides supplemental guidance to implement the requirements of LANL USQ Screening and Determination Standard OST 300-00-06C, and 10 CFR 830.203, as well as the guidance of the Implementation Guide to 10 CFR 830.203 and DOE Order 5480.21.

2.0 SCOPE

The USQ process applies to Hazard Category 2 and 3 nuclear facilities at the Los Alamos National Laboratory (LANL). The USQ standard and procedure provide some in-depth discussion of the expectations of the new 10CFR830.

3.0 DEFINITIONS AND ACRONYMS

The acronyms and definitions of terms that are used in a special way in this procedure are provided in the LANL USQ Screening and Determination Standard OST 300-00-06C.

4.0 RESPONSIBILITIES

USQ Preparers (facility)	♦ Utilize the criteria and guidance in the procedure, in conjunction with OST 300-00-06B, during USQ document preparation to ensure that criteria and expectations are met.
USQ reviewers and approvers	• Utilize criteria in this procedure, in conjunction with procedure FWO OAB –302, USQ Quality Review Process, to review USQs (positive USQDs). These criteria are applicable for facility reviewers as well as FWO-OAB reviewers
USQ Document Samplers	♦ Utilize criteria in this procedure, in conjunction with procedure FWO-OAB-303, USQ Quality Sampling Process, in the review of any USQ document that is evaluated in the FWO-OAB sampling program

5.0 REVIEW PROCESS

5.1 FACILITY PREPARATION AND INTERNAL REVIEW GUIDANCE

Use the information provided in the attached worksheets as a guide to prepare and review USQ Applicability Assessments, USQ Screens, and USQ Determinations. Sufficient supporting documentation must be provided to allow an individual with a

technical/engineering background (i.e. not a Subject Matter Expert) and ultimately DOE to assess that the conclusion reached (USQ process not applicable, change screens out, negative/positive determination) was the correct one.

5.2 POSITIVE USQD QUALITY REVIEW GUIDANCE

The FWO-OAB is required by the UC Contract to review all positive USQDs (USQs) prior to submittal to DOE for approval. The criteria in this procedure must be utilized in the conduct of those reviews.

5.3 USQ PROCESS SAMPLING REVIEW GUIDANCE

The FWO-OAB is required by the UC Contract to perform a sample of nuclear facility USQD documents to determine the extent and quality of application of the USQ process at LANL nuclear facilities. The criteria in this procedure must be utilized in the conduct of those reviews. The process for sampling of LANL nuclear facility USQ documentation by FWO OAB is outlined in the Unreviewed Safety Question Quality Sampling Process Procedure FWO-OAB-303.

5.4 COMMENT RULES

The following rules are to be used by the USQ document reviewers in developing and documenting their comments when the evaluation is conducted to meet the FWO OAB requirement for USQ review and sampling.

Comments are classified as Essential ("E") or Suggested ("S"). Essential comments are those the must be addressed by the document owners. Suggested comments are those that are provided to improve quality of the document and require no response for resolution. The rules that follow will aid the reviewer in determining what kinds of comments are Essential.

Focus on significant deficiencies rather than marginal issues or minor discrepancies. Do not focus on pet issues that are not central to the primary functions of the USQ procedure.

Comments must be based on a failure to adequately address a requirement in 10 CFR 830.203, DOE Order 5480.21, or other applicable requirements documents (e.g., LIRs). The comment should indicate how the deficient item does not comply with the applicable requirement or with DOE interpretations of applicable requirements

Comments should be specific. Avoid general statements that do not clearly identify a deficiency. Personnel resolving the comment should not have to guess at a comment's intent. If material is significantly deficient in content or technical accuracy, the comment should be worded in a way that explains the deficiency. Comments should be "resolvable;" that is, there should be a clear path forward for resolution. If a deficiency is so gross as to require significant effort to understand its nature and devise a path forward, then the reviewer should meet with the FM or FM staff person to discuss the issue and develop a path ahead.

Do not use the USQ standard review process to raise issues that are appropriate for another forum. Examples include issues related to the programmatic mission of the facility or questions about DOE policy that are outside the scope of the USQ.

Do not provide comments that deal with personal preferences. There is more than one way to present material or perform an analysis. Review comments must identify real deficiencies and not promote a different or "better" way of doing something when there is no actual deficiency.

Comments must not ask open-ended questions. If material is confusing such that it is not possible to evaluate adequacy, phrase a comment in terms of the material that is absent or that is not germane to the intended subject.

Comments should offer a resolution to the identified deficiency, if one is known. Resolutions should be based on an applicable standard or requirements document**.**

No "Essential" editorial comments. Editorial errors and improvements should be submitted as "Suggested" comments. The USQ development team should attempt to correct errors to improve the presentation of the material, but "Suggested" comments will not be tracked and do not require resolution. Comments that identify confusing or poorly written material that is impossible to follow or very difficult to understand are not editorial comments. These are deficiencies if the analysis, safety program, activity, etc., is not described adequately and cannot be evaluated.

Review comments should not be submitted just because a reviewer does not have the basic information to determine whether a deficiency actually exists. Comments should be based on knowledge of the USQ process as outlined in the Nuclear Safety Management Rule.

Comments should be worded in a professional manner and tone. Personal insults, innuendo, and harsh remarks are not acceptable and should not be voiced in review comments. Comments should be worded in the spirit of contributing to the goal of producing a quality USQ process. Comments should stick to the facts and be geared toward improving and enhancing the document rather than worded in a negative tenor that displays "one upmanship." The USQ standard review process should not be used to advance personal or organizational agendas.

Comments should not address material that was previously reviewed. Once material has been reviewed and commented on in an interim review, it should not be revisited in subsequent reviews unless it has been revised or other changes were made that affect the subject material. Reviewers are responsible for completing reviews of interim packages and should not consider later reviews an opportunity to "catch up." In addition, if reviewers are replaced, new reviewers should accept the conclusions of earlier reviews unless there are clear and significant deficiencies. ***Exceptions are allowed for new interpretations or guidance provided by DOE between reviews or the adoption of new laboratory requirements.***

ATTACHMENT 1

APPLICABILITY
ASSESSMENT WORKSHEET
GUIDANCE AND REVIEW EXPECTATIONS

NOTE: In the remainder of this document, Guidance and Review Expectations are provided in Italics

Los Alamos NATIONAL LABORATORY	**USQ PROCESS APPLICABILITY ASSESSMENT WORKSHEET**	
Change number:		Date:
Facility-Specific Unreviewed Safety Question Process Applicability Assessment Number:		
Facility Identification:		
Document Title:		

Based on the evaluation presented in this worksheet:

☐ The USQ process is NOT APPLICABLE to this situation, and
- ☐ DOE review and approval is NOT REQUIRED, or
- ☐ DOE review and approval IS REQUIRED, and a Request for Amendment to the Facility Safety Basis should be prepared.

☐ The USQ process IS APPLICABLE, and
- ☐ USQ Screening will be performed
- ☐ Requirements under PISA will be initiated (see section 9.0 of the USQ Standard)

SIGNATURES

Assessor's Signature *This individual must be on a list of USQ qualified personnel.* Typed or printed name of assessor	Date
Assessment Reviewer's Signature *This individual must be on a list of USQ qualified personnel..* Typed or printed name of reviewer	Date
Assessment Approver's Signature *This individual must be on a list of USQ qualified personnel.* Typed or printed name of reviewer	Date
Acknowledging Manager's Signature (OPTIONAL) Typed or printed name of acknowledging manager	Date

Retain original copy per facility records management procedures.

This document was reviewed to ensure proper classification:

☐ Unclassified ☐ UCNI ☐ Classified

This block serves as a reminder that in some cases supporting documentation attached or even titles or names on the cover sheet could be classified. This signature only needs to be obtained if the documentation is submitted for external review (i.e. positive USQDs or those identified for sampling review).

ADC Signature *This signature is only required if document is submitted for external review.* Typed or printed name of ADC	Date
UCNI Reviewing Official Signature *This signature is only required if document is submitted for external review.* Typed or printed name of UCNI reviewing official	Date

APPLICABILITY ASSESSMENT

In assessing the applicability of the USQ process to various situations, it is realized that: (1) some changes do NOT require USQ processing and do NOT require DOE approval, (2) some changes do NOT require USQ processing but DO REQUIRE DOE approval, and (3) if not covered by the first two cases, become mandatory inputs to the USQ process.

*Situations being considered as a result of a **PISA** entry condition (i.e. discrepant as-found conditions, operational events, and receipt of new information) MUST enter the USQ process. Check the appropriate box at the end of this form, complete the cover sheet summary, and continue to the USQ screening and determination form.*

NOTE: The number in brackets following the questions below is a reference to the corresponding section of the standard.

1. If the answer to any of the questions in Section 1 is "Yes," the change does NOT require entering the USQ process and does NOT require DOE approval.

   NOTE: The USQ process not only applies to changes within the boundaries of operations and facilities that require DOE authorization but also to changes outside those boundaries when those changes have the potential to affect the safety of the operations within the boundaries. An example may be a change in location of a fire fighting force credited in the accident analysis and the resulting change in response time.

   a. Is this a maintenance action that involves the replacement of equipment with an exact replacement? [8.2.1.a] ☐ Yes ☐ No

   If the new hardware is an exact replacement, that is, if it has the same make, manufacturer and model number, the action is a pure maintenance repair action, which does not enter the USQ process.

   Maintenance includes activities such as testing equipment to verify that it is operating correctly, testing equipment to ensure that it is in calibration to operate as it was designed, performing actions to prevent failure of equipment, or restoring equipment to the as-designed condition after identification of an equipment failure or malfunction. These conditions do not require entry into the USQ process as long as the facility and site-wide procedures for the conduct of maintenance are followed. The procedures will allow for local screening of maintenance activities to ensure that the requirements to return the system to the as analyzed condition remain in effect. This includes a program of equivalencies for parts in accordance with quality assurance standards when repair parts are not exact replacements (see 1.b below).

   b. Is this a maintenance action that involves the replacement of equipment with an approved equivalent part? [8.2.1.b] ☐ Yes ☐ No

   If the maintenance action is limited to the replacement of an item or component that is an approved equivalent part, that is, if it has the same form, fit, function, and failure modes as determined by an engineering evaluation, the change does not enter the USQ process.

   c. Is this a change to programmatic operations and hardware that remains within the safety envelope already Approved for those operations? [8.2.1.c] ☐ Yes ☐ No

   To make this determination, consider and answer the following questions:

   - *Is there an "approved" hazard analysis that encompasses the programmatic operation?*

   The applicability screen for proposed changes to programmatic or experimental operations presumes that a safety envelope (hazard analysis) has been established for each programmatic operation. As long as the programmatic or experimental safety envelope remains intact, the facility safety basis cannot be infringed. However, if the programmatic or experimental operations have not been the subject of a hazard analysis, The proposed change must enter into the USQ process. An "approved" hazard analysis is one that meets the requirements of OST-300-00-06A, Hazardous Analysis Methodology or is consistent with the methodology used in the currently approved Documented Safety Analysis.

   If the answer to this question is No, then the answer to question 1.c is No. If the answer to this question is Yes, then reference the "approved" hazard analysis in answering the second part of the question below.

   - *Does the existing safety envelope defined by the hazard analysis bound the proposed change?*

   In answering this question, the analyst must address the hazards and controls in the "approved" hazard analysis. The discussion should show that the original hazards and controls will not be affected by the proposed change. That is, no new hazards are introduced and no controls are lessened.

If the answer to this question is No, then the answer to question 1.c is No. If the answer to this question is Yes, then. the answer to question 1.c is Yes, and the proposed change does not enter the USQ process.

d. Is the non-conforming part restored to become compliant with the requirements (i.e. the non-conformance Report is dispositioned "reject" or "rework")? [8.2.1.d] ☐ Yes ☐ No

In a typical QA program, there is a set of standard dispositions for non-conformances. These may include: a "Use-As-Is" disposition in which the non-conforming item is justified as not being the item that was intended but is nonetheless acceptable, a "repair" disposition in which the item is made to agree better with the requirements (but it remains not fully compliant with the requirements), a "rework" disposition in which the item is reworked to the point that it becomes fully compliant with the requirements and a "reject" disposition in which the item is replaced with a fully compliant item. If the disposition of the nonconformance report is reject or rework, then the activity does not enter the USQ process.

Indicate the approved disposition of the nonconformance and answer the question accordingly.

e. Is this change part of a corrective action for a discrepant as-found condition, and is the action a restoration Modification (return to the original condition)? [8.2.1.e] ☐ Yes ☐ No

A discrepant as-found condition may constitute a nonconformance and hence, it might be addressed by the facility quality assurance (QA) process. If the disposition for the discrepant as-found condition or nonconformance involves restoring the equipment, item or component to its original, "as-designed" condition, (sometimes called a "restoration modification), then the "change" does not enter the USQ process.

Indicate whether or not the change or activity involves a "discrepant as-found condition" and, if so, describe how the activity involves restoration to the original design condition. Answer the question accordingly.

NOTE: Do not confuse this with the evaluation of an as-found condition leading to a PISA because the item is described in the DSA! One of the special actions associated with a PISA is the requirement to perform a USQ Determination. This is discussed in more detail in section 2.1 of the USQ Screening form.

f. Is it an editorial change to a procedure or document? [8.2.1.f] ☐ Yes ☐ No

If the change is purely editorial, i.e. has no technical content, it may be eliminated from further consideration In the USQ process, an editorial change may be a spelling or typographical correction, grammatical change, Clarification or additional note or reference. An editorial change does not affect the content, sequence of steps, or intent of the test, process, experiment, programmatic operation, or procedure. For example, correcting typographical errors in a procedure, which do not affect the content, would be inconsequential changes. Note that inconsequential changes do not apply to physical changes to the facility. Also, a change to a design document is considered a physical change.

Justify the decision that the change is editorial in nature (or not) and answer the question accordingly.

NOTE: Editorial changes to TSRs MUST GO TO DOE. See 2.d below.

2. If the answer to any of the questions in Section 2 is "Yes," the change does not require entering the USQ process; however, does require DOE review and approval. Therefore, if there is a "Yes" answer, a Request for Amendment of the Safety Analysis should be prepared (See section 8.6 of the USQ Standard).

a. Is this a change that introduces a new technology to the facility? [8.2.2.a] ☐ Yes ☐ No

Does the change introduce a technology that is new to the facility? If it does, the change is beyond the intended scope of the USQ process.

Approach this question from the standpoint of the existing hazard analyses and safety analyses for the facility. If the "new technology" is encompassed by an existing hazard analysis (for example, a new type of laser in a process that currently uses lasers) or by the facility's existing safety analysis, then it is not new in the sense of the question. Note that "encompassed" means that there are no new hazards or no changes in controls introduced by the "new technology." Conversely, if the "new technology," is not encompassed by existing hazard analyses or the facility's existing safety analysis, then it is "new" in the sense of the question. The USQ process is intended to allow flexibility in making changes in day-to-day operations, but not to exclude DOE in the review of major changes to the facility's

operations.

Justify whether or not the proposed change introduces "new technology" and answer the question appropriately.

b. Is this a change that is a major modification, in that it goes beyond that necessary for day-to-day operations? [8.2.2.b] ☐ Yes ☐ No

Is the new/modified hardware so extensive (More than $1M and/or 4 weeks to implement) as to be beyond that needed to continue day-to-day operations? If so, the change is beyond the intended scope of the USQ process (as envisioned by DOE 5480.21) and hence requires approval by DOE prior to implementation.
CAUTION: *The notion that if DOE has directed a certain course of action, then further DOE approval is not necessary is incorrect. Typically, the parts of DOE that have the funds and authorize programmatic actions have little if any knowledge or involvement in facility safety reviews. Therefore, it is incorrect to assume that if one part of DOE has authorized certain actions, all of DOE has reviewed these actions and that the authorization includes the necessary safety reviews and approvals. The USQ process must therefore be applied to changes directed by DOE.*

c. Has management decided to submit the proposed change to DOE for review and approval? [8.2.2.c] ☐ Yes ☐ No

Management can decide to submit the change voluntarily to DOE for review and approval for reasons that are not related to whether or not a USQ is involved. If management has made such a decision, it is not necessary to complete the USQ process to determine if the change might have been required to be submitted.

d. Is this a change to the TSRs? [8.2.2.d] ☐ Yes ☐ No

Changes to a TSR include editorial changes, the modification of an existing requirement, the addition of a new requirement, or a change to the basis of the TSRs. All changes to the TSRs require DOE safety review and approval. The USQD process is required when the TSR change also requires a change to the DSA.

☐ The USQ process is NOT APPLICABLE to this situation, and
- ☐ DOE review and approval is NOT REQUIRED, or
- ☐ DOE review and approval IS REQUIRED, and a Request for Amendment to the Facility Safety Basis should be prepared.

☐ The USQ process IS APPLICABLE, and
- ☐ USQ Screening will be performed *(NOTE: A hazard/safety analysis must be provided as appropriate)*
- ☐ Requirements under PISA will be initiated (see section 9.0 of the USQ Standard)

Complete the cover sheet summary.

ATTACHMENT 2

USQ SCREENING AND DETERMINATION WORKSHEET GUIDANCE AND REVIEW EXPECTATIONS

NOTE: In the remainder of this document, Guidance and Review Expectations are provided in Italics

Los Alamos
NATIONAL LABORATORY

UNREVIEWED SAFETY QUESTION SCREENING AND DETERMINATION WORKSHEET

Change number:	Date:
Facility-Specific Unreviewed Safety Question Number:	
Facility Identification:	
Document Title:	

Based on the evaluation presented in this report, the change:

☐ has been screened out of the USQ process and does not constitute an Unreviewed Safety Question
☐ does not constitute an Unreviewed Safety Question based on a full USQD
☐ constitutes an Unreviewed Safety Question and **DOE approval is required** prior to implementation

SIGNATURES

Preparer's Signature *This individual must be on a list of USQ qualified personnel.* Typed or printed name of preparer	Date
Reviewer's Signature *This individual must be on a list of USQ qualified personnel.* Typed or printed name of reviewer	Date
Sponsoring Organization Reviewer's Signature Typed or printed name of sponsoring organization reviewer	Date
Approver's Signature *This individual must be on a list of USQ qualified personnel.* Typed or printed name of approver	Date
Acknowledging Manager's Signature *(Optional)* Typed or printed name of acknowledging manager	Date

Retain original copy per facility records management procedures.

This document was reviewed to ensure proper classification:

☐ Unclassified ☐ UCNI ☐ Classified

This block serves as a reminder that in some cases supporting documentation attached or even titles or names on the cover sheet could be classified. This signature only needs to be obtained if the documentation is submitted for external review (i.e. positive USQDs or those identified for sampling review).

ADC Signature *This signature is only required if document is submitted for external review.* Typed or printed name of ADC	Date
UCNI Reviewing Official Signature *This signature is only required if document is submitted for external review.* Typed or printed name of UCNI reviewing official	Date

SECTION 1: INTRODUCTION

1.1 DETAILED DESCRIPTION OF CHANGE

Provide a concise description of the proposed change. Include references to specific FSAR/BIO process descriptions where applicable. This section should clearly explain the relationship of the change to the process. (e.g. is this a component no longer required for the existing process [i.e. a legacy issue], or is this change in preparation for a new process to be approved in a separate USQ. Discuss phases of the project including construction, start-up, normal operation, and provide one-line drawings, logic diagrams, and other reference drawings, as appropriate. Cite MAR and significant chemicals (amount, form, confinement, controls), energy sources and other significant hazards.

NOTE: The number in brackets following the questions below is a reference to the corresponding section of the standard.

1.2 REFERENCES

a) List documents and analyses that constitute the current safety basis for the facility/process

List FSAR/BIO, SER/MER, OSR/TSR/ITSR as applicable.
List DOE approved positive USQDs, if implemented, that have not been incorporated in the current SAR.

b) List other references used to support the evaluation

List documented Telecons and meetings, as applicable, that support the conclusions reached in this document
List Calculations
List Engineering studies, FMEAs, etc.
Facility-Specific Unreviewed Safety Question Process Applicability Assessment Number

c) List hazard analyses/safety analyses that support the conclusions reached in this worksheet

The USQ process is not intended to replace or to serve instead of a safety analysis of the change. The safety implications of a change should be reviewed, analyzed, understood, addressed, determined to be acceptable, and documented by the Laboratory separately from the USQ process. Using the USQ process instead of the safety analysis complicates the USQ process. Further, such a usage is inappropriate because the seven questions to be answered in the USQD are not geared toward understanding whether the change is safe, but rather if any of the probability or consequence risk factors may have increased beyond what has been accepted previously by DOE, and hence if the existing safety controls remain adequate. ***The change should already be known to be safe before it enters the USQ process.*** *The USQ process determines if final approval by the Laboratory is sufficient or DOE review and approval are required. DOE wants to review and approve those changes that involve a USQ (that is, the USQD is positive) to verify that the safety controls are adequate to provide an acceptable level of safety to the public and workers. The existence of a positive USQD does not mean that the change is unsafe, but only that DOE must take the final approval action.*

Reference the documented hazard analysis or safety analysis that addresses the change.

SECTION 2: USQ SCREENING

2.1 Screening – Part I

If a USQD must be performed because USQ screening is not applicable (PISA), complete Section 2.2 and continue to Section 3 to complete the USQD.

The rule requires that a USQ determination must be performed if a PISA exists. A situation involves a PISA if the safety DSA does not describe the facility and its operations accurately. PISA entry conditions may be discrepant as-found conditions, operational events, and receipt of new information. The rule also requires submittal of an evaluation of the safety of the situation regardless of the outcome of the USQD. The USQ process is not intended to replace or to serve instead of the evaluation of the safety of the situation. Note that the corrective action related to a PISA is addressed separately and may not require entering the USQ process.

a. Is this a purely editorial change that does not affect the technical content? [8.3.1.a] ☐ Yes ☐ No

If the paperwork change is purely editorial and has no technical content, it may be eliminated from further consideration within the USQ process. A change to a test, process, experiment, programmatic operation, or procedure that does not affect the content, sequence of steps, or intent of the test, process, experiment, programmatic operation, or procedure is considered a purely editorial change. For example, editorial changes to a procedure, which do not affect the content of the procedure, would be inconsequential changes. Note that editorial changes do not apply to TSRs and inconsequential changes do not apply to physical changes to the facility.

b. Is the change covered by a categorical exclusion? [8.3.1.b] ☐ Yes ☐ No

These are previously analyzed conditions that are documented as full USQ determinations (USQDs) and approved as a Categorical Exclusion by DOE. If the proposed change is bounded by a categorical exclusion, then a full USQD is not required for the change. The Facility Manager maintains a listing of current DOE approved categorical exclusions for use in performing USQDs. The preparer should ensure that the proposed change is completely bounded by the categorical exclusion, particularly noting the assumptions and limitations cited in the categorical exclusion and it's approval documentation.

c. Is this change completely enveloped by a previous USQD? [8.3.1.c] ☐ Yes ☐ No

This screening consideration is intended to avoid unnecessary time and resources. For example, a modification may have been made to a water pump in one area of the facility previously and now it is desired to make the same modification to other water pumps. If, after all differences between the two situations are considered including any differences that might arise because of different uses for the pump, room location and ambient conditions, the modification has been fully addressed by the previous USQD, there is no requirement to repeat that USQD. If the proposed change is covered by a previous USQD, a new USQD is not required. The analyst considers not only the change itself, but also its location, impact on other SSCs and operations, etc., to determine if the proposed change is covered by a previous USQD.

If any answer to any question in Section 2.1 above is "Yes", the change does not require a USQ Determination. Continue to the Summary of Section 2. Otherwise continue below.

2.2 Impacts [8.3.2]

The following section requests that the preparer identify multiple documents, analyses, and SSCs. Although not required by the USQ Standard, it may be useful to compile this information in the form of a checklist to streamline this effort.

a. Identify all Safety Basis documents, procedures, tests and experiments that may be impacted by this change (e.g. FSAR, TSRs, Procedures, etc.) [8.3.2.a]:

Include all applicable Safety Basis documentation. Each document listed here should also be listed in the Reference section. Consider both direct and indirect impacts on each document. If no documents are impacted, state that.

b. Identify all accidents evaluated in the facility Safety Basis that may be impacted by this change [8.3.2.b]:

Identify the design basis accidents, if any, for which failure modes associated with the change can be an initiating event. Discuss the impact of the change on the performance of the safety systems. Briefly discuss how the parameters and systems affected by the change impact the accidents.

c. Identify all SSCs described in the current Documented Safety Analysis that may be impacted by this change [8.3.2.c]:

Include all applicable safety significant and safety class SSCs. Consider both direct and indirect effects. If no SSCs are impacted, state that.

d. Identify all equipment important to safety other than safety SSCs that may be impacted by this change [8.3.2.d]:

Include all applicable equipment important to safety other than safety SSCs. Consider both direct and indirect effects. If no equipment important to safety other than safety SSCs is impacted, state that.

e. Identify credible dominant failure modes, process parameters, and malfunctions associated with this change [8.3.2.e]:

Reference appropriate Hazard and/or Failure Modes and Effects Analyses, and summarize the results of these analyses (related to failure modes) in this section. If there are no new failure modes, process parameters, or malfunctions, state that.

2.3 Screening – Part II

The words "as described in the existing documented safety analysis" identify the key concept for this series of questions. "Description" of the SSCs, procedures, processes, or activities can be explicitly stated in the text, drawings, tables, etc., or only implied. "Safety analysis" is considered the combination of information relating to the control of hazards at a facility (including design, engineering analyses, and administrative controls) upon which DOE depends for its conclusion that activities at the facility can be conducted safely. [DOE 5480.23]. The level of detail in the FSAR/BIO is generally not sufficient for determining whether or not a proposed change meets the "as described in the existing documented safety analysis" criteria. Generally, the facility design basis, physical configuration, and key operating procedures would provide essential supporting documentation for facility SSCs. The goal of these questions is to identify exactly how the proposed change could directly or indirectly impact the facilities SSCs, procedures, processes, or activities. "Other" SSCs that have a safety function identified in the safety basis, even though those safety functions may not have been judged as sufficiently important to warrant the "safety-significant" designation must be included in the assessment.

a. Is this a temporary or permanent change in the facility as described in the existing documented safety analysis? [8.3.3.a] ☐ Yes ☐ No

Is this a change to a Safety SSC?
Is this a change to a SSC important to safety?
Is this a change to Non-safety related equipment that could impact a Safety SSC or a SSC important to safety?
Does this change impact process equipment described in the safety basis?
Does the change alter operating characteristics (response time, flow, amperage draw)?
Does the change add or delete an automatic or manual feature?
Does/could the change introduce a new (possibly unwanted) system interaction?
Does the change alter seismic or environmental qualifications?
Is this a change to a design document? (Design document change = physical change)

If the answer to any of these questions is YES, it will be necessary to prepare a USQD.

The modification of existing hardware (or computer software) and the addition of new hardware (or computer software) are treated as changes to hardware. If a hardware change is being made, in some cases, there will also be changes in the associated procedures or design documents. Therefore, when considering hardware changes, consider also the other screening areas. Changes to equipment that may be described in the safety basis only implicitly may need a USQD prepared. Implicitly described SSCs are those that perform a function that is essential to the performance of the explicitly described equipment. For example, a continuous air monitor must include a vacuum pump to draw the air across a filter medium, a mechanism to move the filter at a predefined rate, a nuclear sensor to measure the activity of the particles collected on the filter, and an alarm mechanism which activates when the measured radiation level exceeds a predetermined set point. Engineering judgment is used to determine if the hardware modification being considered affects one of these implicitly described pieces of equipment. In the situation where the new equipment provides additional protection and would be classified either as a safety-class SSC or as a safety-significant SSC, it warrants having a USQD prepared. Other equipment may also warrant a USQD.

Since all changes to the requirements of the TSRs require DOE safety review and approval, be sure to consider changes to the facility that change the way that OPERABILITY of the TSR could be met.

The Laboratory has decided that changes to hardware/software [for which normal commercial practices may be sufficient and a nuclear-grade formal change control process is not warranted (for example, changes in the administrative areas of a facility where the change has no impact on Material at Risk)], must enter the USQ process to determine if the changes affect whether equipment important to safety can perform its intended function due to the introduction of new interactions and hazards.

b. Is this a temporary or permanent change in the procedures as described in the existing documented safety analysis? [8.3.3.b] ☐ Yes ☐ No

Procedures for operations, surveillance, and maintenance of general systems in the facility are not considered to be implied procedures. However, because of the Quality Assurance considerations, if a system has been classified as a safety SSC, procedures for operations, surveillance, and maintenance for that system are implied directly. The term "surveillance" as used here means those activities that are required by a Surveillance Requirement of the facility TSRs and does not necessarily include all inspections, tests, or calibrations. The need for implementation procedures is obvious for Safety Management Programs that are committed to in the safety basis. For example, a DSA may state that a nuclear criticality safety program will be implemented that conforms to a particular ANSI standard. Then, those top-level procedures necessary to meet this commitment are included implicitly in the safety basis. This criteria does not affect lower tier implementation procedures, so long as the overall effects of changes do not result in a change to the top-level procedures. When changes in the top-level implementing procedures are evaluated in the USQD, it is to be expected that in general the results will be a negative USQD if the description of the safety management program in the safety basis remains correct. That is, if the characteristics of the program that DOE relied upon remain correct, there should

be no increase in any of the USQ risk factors and hence a USQD would be negative. However, in some special cases, DOE may have relied upon a level of detail below the description in the safety basis that would need to be evaluated. New procedures should not be screened out simply because they are not yet described in the safety basis. Engineering judgment is used to decide if the procedure would be identified in an updated SAR/BIO.

If the answer to this question is YES, it will be necessary to prepare a USQD.

c. Is this a test or experiment not described in the existing documented safety analysis? [8.3.3.c] ☐ Yes ☐ No

Written USQ determinations are required for tests or experiments not described in the existing safety analyses. The intent of the criteria of Section 830.203 is to require that safety evaluations be conducted for tests and experiments that are not described in the existing safety basis that might affect safe operations of the facility. By definition, these are tests and experiments that could degrade the margins of safety during normal operations or anticipated transients or degrade the ability of safety SSCs to prevent accidents or mitigate accident conditions. Previously evaluated tests or experiments do not require written USQ evaluations. For example, pre-operational tests, surveillance tests, and functional tests that are described in the documented safety analysis and/or the Technical Safety Requirements do not require the performance of a USQ evaluation every time a test is performed. However, one-of-a-kind tests or experiments used to measure
the effectiveness of new techniques or a new system configuration that might affect safety SSCs will require evaluation before they can be conducted. Post modification testing should be considered and included in the USQ evaluation for the modification. Tests or Experiments that are new to the facility may also involve new hardware or modifications to existing hardware, and new operating procedures or revisions to existing procedures. Therefore, when considering new Tests or Experiments these other areas must be considered also.

If the answer to this question is YES, it will be necessary to prepare a USQD.

Basis for your answers (reference documents reviewed):

If the answer to any question in Section 2.3 above is "Yes", a USQ Determination must be performed. Continue to Section 3 after completing the Summary section below.

USQ Screening Summary:

Based on answers to the screening questions above:

☐ this change does not require a USQ Determination. Complete the cover sheet summary.

☐ this change requires a USQ Determination. Complete Section 3.

SECTION 3: Unreviewed Safety Question Determination (USQD)

In performing the USQD, do not just consider the effects on frequency or consequence to the ultimate receptor (e.g., the dose to the MOI). Rather, consider the effects on key parameters defining the potential malfunction or accident. For accidents, the key parameters to consider are:

- *the unmitigated accident,*
- *preventive measures,*
- *mitigation measures,*
- *initial source term, and*
- *building release fraction.*

The unmitigated accident defines the maximum potential impact of an identified hazard. The initial source term is the primary concern for worker safety and provides the key input into the assessment of public and environmental effects. The building and internal mitigation systems are the ultimate barriers for preventing releases to the environment. The building release fraction defines the forces acting to drive a release from the building and possible release pathways.

For malfunctions of equipment, the key parameters to consider are:

- *root cause of the failure,*
- *effect of the failure on other equipment,*
- *effect of the failure on accident initiation,*
- *effect of the failure on accident progression (i.e. fault tree), and*
- *effect of the failure on accident consequence(s).*

A discernable change to any of the key parameters is considered a positive USQ. In evaluating the effect on these key parameters, consider the aspects that follow:

Unmitigated Accident

- ***Initiating event*** *- this includes the type of event as well as its causes.*
- ***Preventive features*** *- the analyst should consider the effects of the change on administrative control and design features that act to prevent the initial hazard.*
- ***Accident progression*** *- the potential progression of the accident without consideration of mitigation measures.*

Preventive Measures

The analyst should consider the effects of the change on administrative controls and design features that act to prevent the accident. This should include effects of new preventive measures associated with or required by the change.

Mitigation Measures

The analyst should consider the effects of the change on administrative controls and design features that act to mitigate the effects of the accident. This should include effects of new mitigation measures associated with or required by the change.

NOTE: The need for additional protective measures to protect against postulated accidents results in a positive USQD!

Initial Source Term

- ***Material at Risk*** *- This includes consideration of the material type, amount, and form.*
- ***Damage Ratio*** *- This is the fraction of the material at risk that is actually involved in the postulated accident. It includes an assessment of protective barriers.*
- ***Airborne Release Fraction*** *- This includes consideration of potential release mechanisms and the environment in which*

the release takes place.

Building Release Fraction

- ***Leak Pathway*** *- The analyst should consider the form of the initial source, the forces acting to drive a release from the building, and the possible release pathways.*
- ***Removal Mechanisms*** *- The analyst should consider material-removal mechanisms (e.g., deposition, settling, etc.) that may affect the release from the building.*

1. Could the proposed change increase the probability of occurrence of an accident previously evaluated in the documented safety analysis? Explain your answer below. ☐ Yes ☐ No

Discuss each accident listed in section 2.2 separately. Present the frequency category for the proposed change using the appropriate level hazard/accident analysis. Make sure that all assumptions are fully described and supported by the appropriate reference documentation. Consider the general categorization of the accident sequence frequency according to the Likelihood Classification Table in the Hazard Analysis Technical Methodology Handbook (OST 300-00-06A). If the estimated accident probability changes to a more likely bin then the answer to this question is "yes." For an accident that has a point frequency calculation, if the change results in a higher frequency value, then the answer to this question is "yes".

2. Could the proposed change increase the consequences of an accident previously evaluated in the documented safety analysis? Explain your answer below. ☐ Yes ☐ No

Discuss each accident listed in section 2.2 separately. Present the MOI consequence (and where appropriate, the worker consequence) using the appropriate analysis methodology. Make sure that all assumptions (DR, ARF, RF, LPF) are fully described and supported by the appropriate reference documentation. Consequences include the offsite public, the co-located worker, and the involved worker (grabber).

Any potential increase in consequences that is due to any change must be evaluated by comparing the anticipated consequences of an accident with the consequences of a same or similar "type" accident (i.e. accident family) that has already been analyzed.

Note: *Consider not only the bounding accident of a "family" of accidents, but also evaluate all accidents within a family of accidents to ensure that accident consequences don't contribute to the consequences of another accident within the same family, thereby causing it to exceed the existing bounding accident. Ensure that the potential increase in consequences is not due to an accident of a different type (described in Question 5 of this section).*

Assess the unmitigated accident, initial source term, and building release fraction discussed above. Do not consider an increase in consequences to mean simply an increase in the ultimate consequence (e.g., dose to the MOI). Do consider an increase in the potential magnitude of the accident, the initial source term, or the building release fraction to indicate an accident with potential for increased consequences.

Worker and public consequences are initially evaluated in a qualitative manner, using the following categorization technique provided in the Hazard Analysis Technical Methodology Handbook (OST 300-00-06A).. (These consequence categories are from DOE-STD-3011-94.)

*If there is **ANY** increase in consequence the answer to this question is "yes."*

Note that the USQD should not consider common industrial accidents. These are not typically included in the safety basis documentation for the facility and are addressed through other industrial safety programs.

3. Could the proposed change increase the probability of occurrence of a malfunction of equipment important to safety previously evaluated in the documented safety analysis? Explain your answer below. ☐ Yes ☐ No

Refer to section 2.2 for SSCs that may be impacted by the proposed change and for failure modes of these SSCs. Evaluate the change in probability of malfunction of these SSCs in response to the proposed change.

Evaluate the effects of the proposed changes on the functions, methods of performing those functions, and the overall performance of safety class and safety significant systems, structures, and components. Safety class and safety significant SSCs are identified in the facility SAR. Effects of the proposed changes on support systems for SC or SS SSCS should also be evaluated.

Accident analyses often involve calculated or assumed failure of one or more systems important to safety. Other independent systems

important to safety may be assumed to function normally and may even mitigate the severity of the accident. If a proposed change either degrades the performance of these systems or increases the challenges to these systems, the probability will increase that equipment important to safety will malfunction. This value may be determined either qualitatively or by a probability analysis, if the data are available and practical. Credible failure modes associated with the change should be evaluated.

This evaluation should include an assessment of performance degradation and performance requirements.

- ***Performance Degradation*** *- Could the proposed change adversely affect the performance of an SC or SS SSC, even though the SSC may not "fail"? In assessing this impact, consider the SSC performance requirements and the ability of the SSC to meet those requirements with the proposed change. Performance requirements are identified in the facility SAR.*
- ***Performance Requirements -*** *Does the proposed change alter the performance requirements of an SC or SS SSC, such that the ability to meet the altered requirements is reduced? In assessing this impact, consider current performance requirements and potential new requirements for the SSC based on the proposed change.*
- ***Systems Interactions -*** *Could the proposed change adversely affect a support system for an SC or SS SSC or cause some other failure that could indirectly affect an SC or SS SSC? System interactions may include:*
  - *direct interactions (e.g., support systems),*
  - *physical interactions (e.g., physical location of the SSC relative to the proposed change), and*
  - *indirect interactions (e.g., the proposed change could cause an operator to take some action that affects the performance of the SSC).*
- ***Seismic/Environmental Impact -*** *Could the proposed change adversely affect the seismic or environmental qualifications of a SC or SS SSC? Could the proposed change alter the environment under which the SSC must operate?*

If the estimated probability of a malfunction changes to a more likely bin then the answer to this question is "yes." For malfunction that has a point frequency calculation, if the change results in a higher frequency value, then the answer to this question is "yes".

4. Could the proposed change increase the consequence of a malfunction of equipment important to safety previously evaluated in the documented safety analysis? Explain your answer below. ☐ Yes ☐ No

Refer to section 2.2 for SSCs that may be impacted by the proposed change and for failure modes of these SSCs. Evaluate the change in consequence of malfunction of these SSCs in response to the proposed change. Evaluate the change in worker and MOI consequences resulting from a malfunction of these SSCs in response to the proposed change.

Consider the potential effects of a malfunction of SC or SS SSCs on other equipment, accident initiation, and accident consequences. For this assessment, the malfunction is assumed to occur.

This question evaluates changes that affect equipment and thereby potentially increase releases of hazardous material or energy or radioactive doses above the worst-case limiting consequences in the safety basis. Fundamental to this process is evaluating equipment that is important to safety, in relation to the change, to determine if the change could result in increased exposures. The credible failure modes identified in Question 3 should be used in this evaluation.

*If there is **ANY** increase in the consequence of a malfunction the answer to this question is "yes."*

5. Could the proposed change create the possibility of an accident of a different type than any previously evaluated in the documented safety analysis? Explain your answer below. ☐ Yes ☐ No

Refer to the list of accidents presented in section 2.2 and consider the results of any hazard analysis performed. Discuss key accident parameters resulting from the proposed change (MAR amounts and forms, release mechanisms, release pathways, controls, etc.). If these key accident parameters are not bounded by the current accident analysis, this should be considered as a new accident.

Consider each of the elements that define the key accident parameters, as discussed above. For example, this should consider the type, amount, and form of material at risk. In considering these elements, do not discard a new accident scenario simply because an element is "bounded" by analyzed accidents.

The answer to USQ Question 5 should be "Yes" if any element defining the key accident parameters is significantly different from analyzed accidents. An example might be an unanalyzed accident involving the direct release of gaseous radionuclides, where previously analyzed accidents only considered releases of particulate materials and credited HEPA filters. Even if the off-site dose is bounded by the previous analysis, this would be considered a different type of accident.

Also, an accident requiring new mitigation measures would be a different type of accident.

An accident involving an initiator or failure that is not considered in the SAR or other safety document is potentially an "accident of a different type." An accident that may be "different" but involves a smaller accident consequence than that already addressed in the safety documentation should not be considered an accident of a different type, unless the contribution of the accident causes the bounding case to be exceeded. Accidents of a different type are limited to those considered as likely to happen as those considered in the safety basis. See accident type description under "Question 2."

6. Could the proposed change create the possibility of a malfunction of a different type than any previously evaluated in the documented safety analysis? Explain your answer below. ☐ Yes ☐ No

Refer to the list of potential failure modes and/or malfunctions presented in section 1.3 and consider the results of any Hazard or Failure Modes and Effects Analysis performed. If these results are not bounded by the current analysis, this should be considered as a new malfunction.

First identify potential failure modes associated with the proposed change, as they may affect SC or SS SSCs. This should be through a structured hazard assessment technique provided as input to the USQ process. It is not sufficient to simply state the malfunction as "loss of function," but should be at the level where consideration is given to the method by which the function is performed, and thus the method by which the function has failed.

For example, it is not sufficient to state the malfunction of an alarm system as "system fails to alarm," but should consider the underlying methods through which the alarm is given and the subsequent failures that could contribute to the failure to alarm, e.g., loss of power to the instrument, detector failure, miscalibration, alarm circuit failure, etc.

Malfunctions involving equipment not covered by the original safety analysis constitute a "malfunction of a different type."

Exceptions:

- *Malfunctions that may be considered "different" but are bounded by the existing accident analysis are not considered malfunctions of a different type. Possible malfunctions of a different type are limited to malfunctions that are considered as likely to happen as those considered in the safety basis.*
- *Evaluating existing equipment and systems important to safety, in relation to the change, may be necessary to answer Question 6. Relocation, replacement, alteration, redesigning, reconfiguration, change of use, change of power sources, or change of failure mode of equipment may introduce the possibility of a malfunction of equipment important to safety.*

7. Does the proposed change reduce the margin of safety? Explain your answer below. ☐ Yes ☐ No

Consider the impact that the proposed change may have. The reduction of margin of safety must be "clearly discernible". The margin of safety is usually defined as the region between the acceptance limit and the safety limit or failure point of some structure, system, or component (SSC). To evaluate a change in the margin of safety, some limits—described as safety margins—must be established in the safety basis. Normally SSCs and their ranges or limits of operation are described in the basis of the TSRs. Any change that raises the established acceptance limit of any SSC would decrease the margin of safety. Therefore, the answer to this question would be positive, making the change a USQ but only if the reduction of margin of safety is "clearly discernible".

USQ Determination Summary:

If the answer to any question in Section 3 above is "Yes", the proposed change involves an Unreviewed Safety Question. Based on the evaluation above:

☐ this change does not constitute an Unreviewed Safety Question.

☐ this change does constitute an Unreviewed Safety Question (and DOE approval is required prior to implementation).

Complete the cover sheet summary.

ATTACHMENT 3

USQ (POSITIVE USQD) REVIEW CHECKLIST

USQ Review Checklist

Document Title:	
Document number:	
Reviewer:	

Review Criterion	Yes	No	N/A	Comment
Cover Sheet Have all required fields been properly completed? Are all individuals USQ qualified (i.e. is training current)? Was the document reviewed to ensure proper classification (e.g. UCNI)?				
Detailed Description of Change - (Section 1.1) Is the description of the change, in conjunction with the cited reference materials, sufficient to judge the potential impact of the proposed change on the facility authorization basis? Are material types, quantities, forms and confinement described? Are hazardous equipment items described?				
References – (Section 1.2) Have all elements of the facility authorization basis that may be impacted by the change been identified? Are reference materials complete, current and appropriate?				
Screening Part I – (Section 2.1) Have the USQ screening questions been answered correctly?				
Has adequate justification for the answers been provided?				
Impacts – (Section 2.2)				
Have all facility documents, analyses, and SSCs that may be impacted by the change been identified?				
Screening Part II – (Section 2.3) Have the USQ screening questions been answered correctly?				
Has adequate justification for the answers been provided?				

USQ Determination/Seven Questions – (Section 3.0)				
1. Could the Proposed Change Increase the Probability of Occurrence of an Accident Previously Evaluated in the Documented Safety Analysis? Has the probability of accidents associated with the change been assessed adequately? Have all applicable accidents been considered? Has adequate justification for the answer to this question been provided?				
2. Could the Proposed Change Increase the Consequences of an Accident Previously Evaluated in the Documented Safety Analysis?				
Have the consequences of accidents associated with the change been assessed adequately? Have all applicable accidents been considered? Has adequate justification for the answer to this question been provided?				
3. Could the Proposed Change Increase the Probability of Occurrence of a Malfunction of Equipment Important to Safety Previously Evaluated in the Documented Safety Analysis?				
Has the probability of malfunctions of equipment important to safety associated with the change been assessed adequately? Have all applicable malfunctions and equipment been considered? Has adequate justification for the answer to this question been provided?				
4. Could the Proposed Change Increase the Consequence of a Malfunction of Equipment Important to Safety Previously Evaluated in the Documented Safety Analysis?				
Have the consequences of malfunctions of equipment important to safety associated with the change been assessed adequately? Have all applicable malfunctions and equipment been considered? Has adequate justification for the answer to this question been provided?				

5. *Could the Proposed Change Create the Possibility of an Accident of a Different Type than any Previously Evaluated in the Documented Safety Analysis?*				
Have the types of accidents associated with the change been adequately characterized? Have differences in important accident parameters been considered in assessing whether, or not, an accident may be of a different type? Has adequate justification for the answer to this question been provided?				
6. Could the Proposed Change Create the Possibility of a Malfunction of Equipment Important to Safety of a Different Type than any Previously Evaluated in the Documented Safety Analysis?				
Have the types of malfunctions of equipment important to safety associated with the change been adequately characterized? Does the assessment adequately consider whether, or not, there may be new equipment which should be designated as important to safety? Has adequate justification for the answer to this question been provided?				
7. *Does the Proposed Change Reduce the Margin of Safety?*				
Have all margins of safety which might possibly be challenged by the change been identified? Has the margin of safety associated with the change been properly characterized? Has adequate justification for the answer to this question been provided?				
USQD Summary				
Has the USQD been properly classified?				
Overall:				
Has the USQ been documented in accordance with the facility-specific USQD procedure? Have all calculations supporting this USQD been spot checked and found to be accurate and appropriate?				

Has a complete set of backup and reference documentation been provided to or otherwise made available to the reviewer?				

ATTACHMENT 4

REVIEW COMMENT TRANSMITTAL FORM

Comment Transmittal Form

Comment #	Category (E or S)	Reviewer	Section	Comment	Response/Resolution	Status

Note: E = Essential; S = Suggestion;

Guide for completing form by Column entry:

1. **Comment #:** Comment number will be generated when comments from the various reviewers are consolidated by the Team Leader. Therefore, you cannot cross reference to a previous comment effectively.
2. **Category (E or S):** See the Comment Rules for assignment of Comment Category, Essential or Suggested.
3. **Reviewer:** Reviewer initials should go in here. If there is more than one reviewer with the same initials, then the Team Lead will work to resolve the problem.
4. **Section:** Enter the page number, paragraph number, or line number to best define the source of the comment. You may also use Figure, Table, or any other designator that will aid the document owner in understanding the comment.
5. **Comment:** Document comment in accordance with section 5.4 rules.
6. **Response/Resolution:** This is reserved for the document owner.
7. **Status:** This is used by the Team Leader to track the status (open/closed) of the comment. You will be asked to provide appropriate closure information – that is, the comment is closed when the resolution is accepted.